

**Before the
Federal Communications Commission
Washington, DC 20554**

In the Matter of

DexCom, Inc.

Request for Waiver of the Frequency
Monitoring Requirements of the
Medical Implant Communications
Service Rules

ET Docket No. 05-213

COMMENTS OF MEDTRONIC, INC.

MEDTRONIC, INC.

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July 15, 2005

SUMMARY

DexCom is requesting a permanent waiver of the Medical Implant Communications Service (“MICS”) smart radio regulations to authorize operation of RF devices that do not listen before transmitting (“LBT”) and are not frequency agile. These devices and other similar non-compliant devices can cause interference to MICS-compliant devices. The 402-405 MHz MICS band is a poor choice for such operations, as it would limit the band’s ability to support reliable and much needed, interference-free, life-critical communications well into the future.

Unlike DexCom, other manufacturers, including Medtronic, have developed wireless blood glucose monitoring systems that operate in compliance with FCC Rules in other parts of the spectrum. Nevertheless, Medtronic recognizes that there is a growing need for spectrum that can be harmonized for use in many parts of the world and will support medical devices that do not require the transmission of time-sensitive, life-critical data. For this reason, Medtronic has proposed the Medical Data Service (“MEDS”) to operate on a secondary basis at 401-402 and 405-406 MHz (spectrum occupied by METAIDS users). These bands would be appropriate for DexCom’s blood glucose sensors and other simple, transmit-only devices, as the MEDS would allow lower-power, low-duty-cycle transmissions from implanted and body-worn medical devices that do not perform LBT and are not frequency agile.

If the Commission determines that DexCom deserves to be authorized by waiver, the relief that issues should be a conditional temporary waiver of the Part 15 requirements to permit operation in 401-402 or 405-406 MHz. The Commission should not compromise the MICS band at 402-405 MHz through issuance of a waiver of the smart radio rules.

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Medtronic respectfully submits these comments on DexCom, Inc.'s ("DexCom's") request for waiver of the smart radio regulations in the Commission's Medical Implant Communications Service ("MICS").¹ DexCom is seeking a permanent waiver of the MICS smart radio regulations on an expedited basis to allow operation of glucose sensing RF devices that are not frequency agile and do not listen before transmitting ("LBT").²

The Commission has repeatedly recognized that the MICS smart radio regulations serve a vital public interest need.³ The regulations ensure that low-power RF implanted medical

¹ See 47 C.F.R. §§ 95.628(a), 95.1209(b), and 95.1211(b) (2005). The MICS operates at 402-405 MHz on a secondary non-interference basis to primary Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services (collectively "METAIDS").

² See 47 C.F.R. § 1.925 (2005).

³ See Biotronik, Inc. Equipment Authorization for the Medical Implant Communications Service, FCC Identifier PG6BAOT, *Memorandum Opinion and Order*, 18 FCC Rcd 3027 (2003) ("2003 MICS Order") at ¶¶ 15, 18. See also Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, *Report and Order*, 14 FCC Rcd 21040 (1999) ("1999 MICS R&O").

equipment can successfully share the limited MICS spectrum and support reliable communications links with external control and monitoring equipment. Indeed, other medical device manufacturers are developing products and applications that take full advantage of the FCC's smart radio rules using fully compliant, low-power, miniaturized transceivers.

All MICS devices must support LBT. Devices that do not, such as DexCom's glucose sensors, can interfere with implanted MICS devices communicating time-sensitive, life-critical medical data. In fact, allowing non-LBT devices pursuant to a waiver effectively penalizes medical device manufacturers that have invested in the development of compliant products. More importantly, proliferation of non-LBT devices in the MICS band sets the stage for the detriment of those members of the public who will need to rely on time-sensitive, life-critical communications in the MICS band.

At the same time, Medtronic acknowledges the need for additional spectrum to support low-cost, low-power transmitter for wireless medical applications. With this in mind, the company recently filed a petition for rulemaking asking the FCC to establish the Medical Data Service ("MEDS") at 401-402 and 405-406 MHz⁴ – spectrum adjacent to the MICS band, which like the MICS would be licensed by rule. While Medtronic strongly opposes any waiver of the MICS smart radio regulations, if the FCC is inclined to allow DexCom to operate its RF medical devices pursuant to a waiver, the agency should grant DexCom a conditional waiver to operate its devices in the proposed MEDS bands for two years or until the agency promulgates rules authorizing low-power medical operations in those bands. The proposed MEDS would allow lower-power, low-duty-cycle transmissions from implanted and body-worn medical devices such as DexCom's glucose sensors that do not perform LBT and are not frequency agile.

⁴ A copy of the MEDS petition for rulemaking is attached to these comments. *See* Exh. A.

I. THE COMMISSION’S MICS SMART RADIO REGULATIONS MUST BE UPHELD.

The MICS smart radio regulations serve a vital public need – the necessity of reliable, interference-free, real-time communications between implanted medical devices and external monitoring and control equipment. In the very near future, many patients will be relying upon intelligent medical implants to communicate time-sensitive medical information. To the extent possible, smart radio technology ensures that such information can be transmitted reliably on a real-time basis. Allowing non-compliant (*i.e.*, non-LBT and non-frequency agile) devices, such as the DexCom sensors, in the band would eviscerate the MICS long-term viability for vital medical uses.

A. Waiver Of The MICS Smart Radio Regulations Would Not Be In The Public Interest.

It is a well established principle that the Commission will waive its rules only if it determines, after careful consideration, that such a grant would serve the public interest without undermining the policy which the rule in question is intended to serve.⁵ DexCom has not shown that waiver of the MICS smart radio regulations would be in the public interest. Indeed, the Commission has repeatedly recognized the fundamental importance of these regulations.⁶ The proliferation of devices such as DexCom’s that transmit without sensing the channel could interfere with compliant devices that perform LBT and are frequency agile. Upholding the MICS smart radio regulations will support well into the future the viability of MICS applications that relay time-sensitive, life-critical information.

⁵ See *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C. Cir. 1969). See also 47 C.F.R. § 1.925 (2005).

⁶ See 2003 MICS Order at ¶¶ 15, 18; 1999 MICS R&O. See also Cognitive Radio Technologies and Software Defined Radios, *Report and Order*, FCC 05-57, Mar. 11, 2005.

There is no question that the MICS smart radio regulations serve the public interest. The FCC implemented these regulations to ensure that medical devices would be able to share successfully the limited MICS spectrum with the primary METAIDS users of the band and with other MICS devices operating in the band, even in hospital environments where ambient background noise levels can be extremely high.⁷ As the Commission declared in the *MICS Report and Order*, “[w]e believe that the adopted rules will allow use of newly-developed, life-saving medical technology without harming other users of the frequency band.”⁸ And, in proposing the MICS rules, the FCC emphasized: “[w]e believe that the potential for interference between multiple MICS systems operating in the same area must be minimized to prevent adverse effects on patients.”⁹ Thus, consistent with the FCC’s intentions when it established the MICS, communications among devices that can sense the spectrum environment and operate in clear spectrum will be much more reliable than devices, like DexCom’s, that do not.¹⁰

⁷ See *MICS Report and Order* at ¶¶ 3-5, 8, 15-16; see also 47 C.F.R. § 95.1211(b) (“Channel use policy. ... Those using MICS transmitters must cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities. Channels must be selected in an effort to avoid interference to other MICS transmissions.”).

⁸ See *MICS Report and Order* at ¶ 15. MICS smart radio technology will support an ever-expanding variety of medical applications. These include the monitoring and regulation of heart activity, treatment of Parkinson’s disease, controlling neuro/muscular impairment, dispensation of pharmaceuticals, and fertility monitoring. See OFCOM – Federal Office of Communications, Short Range Devices ... Overview and Latest Developments, Switzerland, Rev. 2, Feb. 20, 2003, at 14-15 (“With the rapid pace of technological development permitting the micro-miniaturisation of electronic circuitry, there is likely to be an ever-expanding list of applications where active medical implants will drastically improve the quality of life for affected patients.”). See also ITU-R SA.1346, Annex 1, Section 1.

⁹ Amendment of Parts 2 and 95 Of The Commission’s Rules To Establish A Medical Implant Communications Service In The 402-405 MHz Band, *Notice of Proposed Rulemaking*, 14 FCC Rcd 3659, 3660 ¶ 10 (1999).

¹⁰ Although DexCom’s application does not require reliable communications, non-compliant medical operations in the MICS band will affect the reliability and viability of MICS applications that require time-sensitive data transfer from implants.

Contrary to DexCom's statement that its devices "will not interfere with other MICS users,"¹¹ if non-compliant devices like DexCom's are given an unfettered right to transmit at will within the MICS band, the impact on patients using MICS-compliant devices to communicate time-sensitive, life-critical data could be severe. In fact, it is not possible to assess fully the interference impact of the DexCom devices based on the limited disclosure in the waiver request. DexCom, for instance, did not disclose the actual radiated transmit power level, *i.e.*, Equivalent Isotropically Radiated Power, or EIRP, of its devices.¹² The Request states only that the EIRP is *less than 25* microwatts. As a matter of fact, DexCom's failure to disclose key RF system operating parameters or provide a complete description of its sensor systems makes it impossible to assess fully the interference impact of its devices on other low-power medical devices.

Based on the information provided in the Request, it also is not possible to assess fully the interference impact that other spectrum users will have on the DexCom device. In contrast to DexCom's claims,¹³ NTIA has found that other similar non-compliant devices would be susceptible to interference from primary METAIDS users.¹⁴ Because METAIDS radiosondes

¹¹ Request at 8.

¹² See Request at 8 (conducted power level peaks at "-20 dBm conducted, which is less than the maximum EIRP of 25 microwatts ordinarily authorized for MICS transmitters.") DexCom provides no information on the gain of its antenna. The Request only states that its system has a range of 5 feet. A system that has a range of only 5 feet can operate with an EIRP that is substantially less than 25 microwatts. Conversely, a system with 25 microwatts EIRP can operate over a distance that is much greater than 5 feet.

¹³ See Request at 9 ("There is no realistic risk of interference caused to DexCom's system from other MICS users or from primary users of the 402-405 MHz band, including the National Weather Service weather balloons.").

¹⁴ See Letter from Fredrick R. Wentland, Associate Administrator, NTIA Office of Spectrum Management, to Edmond J. Thomas, Chief, FCC Office of Engineering and Technology, May 22, 2003, ET Docket No. 03-92 (METAIDS presents a "very real" risk of interference to non-compliant devices). See also Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, Order, 19 FCC Rcd 4208, ¶ 16 (2004) ("Biotronik Waiver Order"). Because the federal

are launched and landed throughout the United States on a regular basis, NTIA has expressed concern with the “potential difficulties that might arise if the radiosondes interfere[] with the reception of critical medical data.” In fact, medical implants are more susceptible to interference from other users of the spectrum because the implants must transmit with very low transmit power levels to conserve battery power.

In addition, many international regulatory bodies call for smart radio technology for medical implant communications systems operating at 402-405 MHz.¹⁵ The technology is necessary to “avoid interferers and support the simultaneous operation of multiple devices in the same area (such as clinics with multiple rooms).”¹⁶ Thus, as these regulatory bodies understand, reliable, interference-free communications from medical implants is vitally important.

government uses the 401-406 MHz band for the METAIDS, NTIA has a substantial interest in assessing DexCom’s request for permanent waiver of the MICS smart radio rules.

¹⁵ This includes the ETSI and the International Telecommunications Union (“ITU”). See European Standard ETSI EN 301 839 V1.1.1 (2002-06), *Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio Equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1* at 29-38; see also Recommendation ITU-R SA.1346, Sharing Between The Meteorological Aids Service and Medical Implant Communications Systems (MICS) Operating in the Mobile Service In the Frequency Band 401-406 MHz, Annex A.

In addition, Industry Canada has adopted the MICS spectrum sharing requirements. See Active Medical Implant Communications System Devices in the 402-405 MHz Band, Industry Canada, Spectrum Management and Telecommunications Policy, Radio Standards Specification, RSS-243, Issue 1, July 2004 available at [http://strategis.ic.gc.ca/epic/internet/insmt-gst.nsf/vwapj/rss243e.pdf/\\$FILE/rss243e.pdf](http://strategis.ic.gc.ca/epic/internet/insmt-gst.nsf/vwapj/rss243e.pdf/$FILE/rss243e.pdf) last accessed July 15, 2005. The New Zealand Ministry of Economic Development also has proposed allocating 402 to 405 MHz for low-power biomedical telemetry applications. See Short Range Devices Discussion Paper, Summary of Submissions and Conclusions, Dec. 2004, New Zealand Ministry of Economic Development, Radio Spectrum Policy and Planning, available at <http://www.med.govt.nz/rsm/planning/srd/submissions-summary/submissions-summary.pdf> last accessed July 15, 2005.

¹⁶ See ITU-R SA.1346 at Annex 1, §§ 2, 3.1, and 4.2. The ITU also noted that “[i]nternational spectrum studies have shown that even with 3 MHz available only one or two channels will be usable in many environments.”

Accordingly, for good reason, smart radio technology is a cornerstone of the MICS.¹⁷ Simply put, it is smart spectrum policy.¹⁸ Implementation of the technology in the MICS band is an effective self-regulating approach that promotes spectrum efficiency through avoiding the creation and receipt of interference. Also, smart radio technology is flexible enough to support America's emerging medical applications and evolving medical implant needs well into the future.

B. DexCom Has Available Other Reasonable Alternatives.

As outlined above, DexCom has not shown that waiver of the MICS smart radio regulations is in the public interest. Moreover, DexCom has available other reasonable alternatives.¹⁹ DexCom could have developed a system that operates in spectrum outside of the MICS band like several of its competitors have,²⁰ or it could have developed a system that complies with the MICS rules. Contrary to DexCom's claims that MICS technology "does not

¹⁷ See 47 C.F.R. §§ 95.628, 95.1211(b).

¹⁸ It is fully consistent with the recommendations of the Commission's Spectrum Policy Task Force, a critically important body that set forth sound policy recommendations, and, in effect, the agency's spectrum agenda over the last several years. See FCC Spectrum Policy Task Force Report, Nov. 1, 2002, ET Docket No. 02-135 ("SPTF Report"); see also Cognitive Radio Technologies and Software Defined Radios, *Report and Order*, FCC 05-57, Mar. 11, 2005.

¹⁹ See *Pacific Microwave Joint Venture*, 15 FCC Rcd 11704, 11706 ¶ 7 (2000) ("PMJV has failed to demonstrate that there are no reasonable alternatives to utilizing common carrier frequencies to serve its own customers. ... That these alternatives could cause PMJV to incur additional equipment costs is not, by itself, sufficient grounds for granting a waiver. ... Therefore, we believe that reasonable alternatives that are consistent with the Commission's Rules and in furtherance of the public interest are available to PMJV.") (citations omitted).

²⁰ TheraSense, for example, makes a blood glucose monitor, which is very similar to the DexCom system, that operates in Part 15 spectrum at 315 MHz. See User Manual, TheraSense Continuous Glucose Monitoring System, submitted with equipment authorization application for FCC ID: QXS-TX030301. Abbott Laboratories acquired Therasense in 2004.

Medtronic MiniMed also offers similar blood glucose monitoring systems that operate outside of the MICS band at 418 MHz and 916.5 MHz.

exist,”²¹ ultra-low-power MICS transceiver chips are now available from a number of sources, and compliance with the MICS smart radio regulations is fully within the state of the art.

RF chip manufacturers Cambridge Consultants²² and Zarlink Semiconductor²³ have introduced miniaturized low power drain smart radio transceivers that comply with the FCC’s MICS rules. In fact, Zarlink expressly notes that its MICS-compliant chip may be used to facilitate communications with implanted blood glucose sensors.²⁴ Another chipmaker, AMI Semiconductor is developing MICS-compliant medical devices with Interventional Rhythm Management, a cardiac device maker.²⁵ Medtronic itself received a FCC authorization for its external MICS programmer controller, and in September 2003 demonstrated a MICS-compliant

²¹ Request at 11.

²² See David Manners, *Low power radio for in-body medicine*, ELECTRONICSWEEKLY.COM, Jan. 18, 2005, available at <http://www.electronicweekly.co.uk/Article38546.htm> last accessed July 15, 2005.

²³ See Susan Taylor, *Zarlink Unveils Wireless Chip For Medical Implants*, WASHINGTONPOST.COM, May 31, 2005 (“Zarlink’s high-speed chip transmits about ten times the data of rival products, while consuming about 20 percent of the power The chip’s minuscule appetite for power means it can deliver additional features without significantly draining a device’s battery.”).

²⁴ *Zarlink Introduces World’s First Wireless Chip Designed Specifically for In-Body Communication Systems; Merging RF and ultra low-power expertise, ZL™70100 transceiver chip fully complies with MICS (Medical Implant Communication Service) standard; Applications include implanted pacemakers, defibrillators, neurostimulators and blood glucose sensors*, Press Release, May 31, 2005, available at <http://news.zarlink.com/archive/2005/May/31/May31-ZL70100-English.htm.en> last accessed July 15, 2005. The data sheet for the Zarlink chip is available at http://products.zarlink.com/product_profiles/ZL70100.htm.

²⁵ See AMI Semiconductor Agreement With Interventional Rhythm Management, Inc. Will Deliver Mixed-Signal Semiconductors for Next-Generation Implantable Defibrillators and Pacemakers – Turnkey ASIC Solutions for Cardiac Electrophysiology Devices Will Meet Requirements for Low Power Operation and Low Data Rate MICS Wireless Communications, AMI Press Release, Apr. 18, 2005, available at http://www.amis.com/news/releases/2005/Q2/050418_irm.html last accessed July 15, 2005. Their initial product is going to be an intravascular defibrillator designed to prevent sudden cardiac death. The data sheet for the AMI Semiconductor chip is available at http://www.amis.com/pdf/amis_52100_fs.pdf

implant device to FCC staff. The company expects that its MICS-compliant implants will be generally available in the first quarter of 2006.

C. If Any Waiver Is Granted, It Should Be A Waiver To Operate Outside Of The MICS Band at 401-402 or 405-406 MHz.

If the FCC grants DexCom a permanent waiver to operate its non-compliant medical devices in the MICS band, it will send the wrong message to medical manufacturers that have worked to develop compliant products. Indeed, it is troubling that DexCom chose to develop a non-compliant product and strategically waited to petition the FCC for relief until the eve of its expected release.

Notwithstanding, Medtronic recognizes the need for spectrum that will support low-power, low-cost transmit-only medical devices, such as DexCom's blood glucose sensor application. With this and other important medical applications in mind, Medtronic filed a petition for rulemaking to establish the Medical Data Service ("MEDS") at 401-402 and 405-406 MHz – spectrum that is adjacent to the MICS band. The MEDS would support short-range data communications among implanted and body-worn medical devices to support, *inter alia*, Patient Area Networks.

The DexCom Short Term Sensor ("STS") is apparently a transcutaneous device – the sensor portion is inserted into the body and the RF transmitter remains outside the body. If so, operation would not be permitted in the MICS even if the device did support LBT and frequency agility. However, the device appears to be well suited for the MEDS.²⁶ The MEDS would allow lower power, low-duty-cycle operation from RF medical devices such as the DexCom glucose sensors that perform non-emergency medical monitoring and reporting functions.

²⁶ See Exh. A, MEDS Petition for Rulemaking.

If the FCC is inclined to allow DexCom to operate its RF medical devices pursuant to a waiver, the agency should issue a conditional waiver of the Commission's Part 15 Rules to allow temporary operation in one of the proposed MEDS bands at 401-402 or 405-406 MHz. To limit the impact of the devices on existing operations, any waiver also must include the following conditions, consistent with the conditions in the *Biotronik Waiver Order*.²⁷

- Marketing and implantation of the non-compliant devices is limited to two years from the date of issuance of the Commission's order. After that time, devices implanted pursuant to the waiver can continue to operate, but no additional devices can be implanted pursuant to the waiver.
- It applies only to subcutaneous and transcutaneous equipment and not to any equipment that is entirely external to the body.
- Operation is limited to non-life critical, non-emergency communications, the failure of which will not impact the health or safety of the patient using the device.
- Operation under the waiver is limited to the device characteristics stated in DexCom's Request for Waiver and any follow-on filings that fully disclose the device's actual radiated transmit power and operational characteristics.
- Medical professionals and patients must be given prior notice that interference from METAIDS radiosondes to such devices is a very real possibility and DexCom must provide instructions and procedures that medical professionals and patients should follow to mitigate any interference.
- Medical professionals and patients must be given notice of each of the other conditions placed on the DexCom equipment.

²⁷ The FCC placed very similar conditions on the Biotronik line of transmit-only implants, based, in part, on conditions that NTIA requested. See *Biotronik Waiver Order*, ¶ 20.

CONCLUSION

For the foregoing reasons, the Commission should not grant DexCom a waiver to operate its devices in the MICS band. Should the FCC decide, nonetheless, to authorize operation of the DexCom devices pursuant to a waiver, it should be a temporary waiver to operate at 401-402 or 405-406 MHz and include the conditions detailed above.

Respectfully submitted,

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